EXHIBIT 18

UROGYNECOLOGY

Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study

Sara Abbott, MD; Cecile A. Unger, MD, MPH; Janelle M. Evans, MD; Karl Jallad, MD; Kevita Mishra, MD; Mickey M. Karram, MD; Cheryl B. Iglesia, MD; Charles R. Rardin, MD; Matthew D. Barber, MD, MHS

OBJECTIVE: The purpose of this study was to describe the evaluation and management of synthetic mesh-related complications after surgery for stress urinary incontinence (SUI) and/or pelvic organ prolapse (POP).

STUDY DESIGN: We conducted a multicenter, retrospective analysis of women who attended 4 US tertiary referral centers for evaluation of mesh-related complications after surgery for SUI and/or POP from January 2006 to December 2010. Demographic, clinical, and surgical data were abstracted from the medical record, and complications were classified according to the Expanded Accordion Severity Classification.

RESULTS: Three hundred forty-seven patients sought management of synthetic mesh-related complications over the study period. Index surgeries were performed for the following indications: SUI (sling only), 49.9%; POP (transvaginal mesh [TVM] or sacrocolpopexy only), 25.6%; and SUI + POP (sling + TVM or sacrocolpopexy), 24.2%. Median time to evaluation was 5.8 months (range, 0–65.2). Thirty percent of the patients had dyspareunia; 42.7% of the patients had mesh erosion; and 34.6% of the patients had pelvic pain. Seventy-seven percent of the patients had a grade 3 or 4 (severe) complication. Patients with TVM or sacrocolpopexy were more likely to have mesh erosion and vaginal symptoms compared with sling only. The median number of treatments for mesh complications was 2 (range, 1–9); 60% of the women required ≥2 interventions. Initial treatment intervention was surgical for 49% of subjects. Of those treatments that initially were managed nonsurgically, 59.3% went on to surgical intervention.

CONCLUSION: Most of the women who seek management of synthetic mesh complication after POP or SUI surgery have severe complications that require surgical intervention; a significant proportion require >1 surgical procedure. The pattern of complaints differs by index procedure.

Key words: mesh excision, mesh-related complication, sling, synthetic mesh

Cite this article as: Abbott S, Unger CA, Evans JM, et al. Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study. Am J Obstet Gynecol 2014;210:163.e1-8.

Approximately 11% of women in the United States will require surgical intervention for either pelvic organ prolapse (POP) or stress urinary incontinence (SUI) by age 80 years. Of these women, up to 29% will undergo repeat surgery for symptom recurrence.[1,2] In response to these high recurrence rates, the placement of synthetic mesh during repair is being used increasingly in hopes of achieving more durable improvement.[3] Current evidence suggests that, although the use of such mesh may reduce objective symptom recurrence when compared with native tissue repair only, complications appear to increase.[4-6] Common complications include intraoperative bladder perforation, mesh erosion, chronic pelvic pain, dyspareunia, infection, and fistula formation.[4-16]

How to best balance the potential benefit of improved outcomes with the well-demonstrated risk of repair-related complications remains unclear. The Food and Drug Administration has responded by first issuing a public health warning in October 2008, which was followed by a safety communication in July 2011.[17,18] These warnings highlight the need for a thorough informed consent process but leave the ultimate decision regarding the use of synthetic mesh between clinician and patient. The purpose of this study was to describe the evaluation and management of complications from synthetic mesh after surgery for SUI and POP that were evaluated at 4 US tertiary referral centers. Results were intended to help elucidate the nature of possible complications, the context/circumstances in which they are most likely to occur, and the additional treatment that is typically required for managing these complications.

From the Center for Urogynecology and Reconstructive Pelvic Surgery, Obstetrics, Gynecology and Women's Health Institute, Cleveland Clinic, Cleveland (Drs Abbott, Unger, and Barber), and Advanced Urogynecology and Pelvic Surgery, The Christ Hospital, Cincinnati (Drs Evans and Karram), OH; Department of Urogynecology, MedStar Washington Hospital Center, Washington, DC (Drs Jallad and Iglesia); and Department of Urogynecology, Women & Infants Hospital of Rhode Island, Providence, RI (Drs Mishra and Rardin).

Received Aug. 7, 2013; revised Sept. 23, 2013; accepted Oct. 10, 2013.

Supported by the Foundation for Female Health Awareness, The Christ Hospital, Cincinnati, OH.

The authors report no conflict of interest.

Presented at the 33rd Annual Scientific Meeting of the American Urogynecologic Society, Chicago, IL, Oct. 3-6, 2012.

Reprints: Matthew Barber, MD, MHS, Mail Code A81, 9500 Euclid Ave., Cleveland, OH 44195. barberm2@ccf.org.

TABLE 1
Current Procedural Terminology and *International Classification of Diseases*, 9th Revision, codes used to identify potential subjects

Type of code	Code and explanation
Current Procedural Terminology	57267 Insertion of mesh or other prosthesis for repair of pelvic floor defect
	57295 Revision or removal of prosthetic vaginal graft (vaginal approach)
	57296 Revision or removal of prosthetic vaginal graft (abdominal approach)
	57426 Revision or removal of prosthetic vaginal graft (laparoscopic approach)
	57287 Revision or removal of sling for stress incontinence
International Classification of Diseases, 9th Revision	619.0 Fistula involving female genital tract
	623.2 Vaginal stricture
	625.0 Dyspareunia
	625.5 Pelvic pain syndrome
	625.9 Pelvic pain unspecified
	719.45 Pain, joint, pelvic region
	729.6 Foreign body in soft tissue
	788.20 Retention of urine
	788.21 Incomplete bladder emptying
	936 Foreign body in intestine or colon
	938 Foreign body in alimentary tract
	939.0 Foreign body in bladder or urethra
	939.2 Foreign body vulva or vagina
	939.9 Foreign body in genitourinary tract
	959.9 Foreign body
	996.30 Mechanical complication of genitourinary device implant and graft
	996.65 Infection and inflammatory reaction because of genitourinary device, implant, or graft
	996.76 Mesh erosion
	V58.32 Removal of suture

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014.

Materials and Methods

This was a multicenter, retrospective analysis of all women who attended 4 US tertiary referral centers for evaluation and/or management of a complication that resulted from synthetic mesh placed during surgery for SUI and/or POP. The 4 sites included Cleveland Clinic (Cleveland, OH), The Christ Hospital (Cincinnati, OH), MedStar Washington Hospital Center (Washington, DC), and Women & Infants Hospital of Rhode Island (Providence, RI). All sites obtained individual institutional review board approval.

All sites underwent training to follow standardized data abstraction procedures. To identify potential subjects, a search of the medical/billing records was performed with the use of a uniform set of Current Procedural Terminology and International Classification of Diseases, 9th Revision, codes (Table 1). To reduce irrelevant results, sites were allowed to limit their search to patients of only those practitioners (including both gynecologists and urologists) who were known to have managed vaginal mesh complications. The charts of all potential subjects were screened by site-specific study personnel to determine whether eligibility criteria were met. To qualify for inclusion in the study, the patient had to undergo the index surgery in which synthetic mesh was initially placed on or after Jan. 1, 2006. Selection of this date was intentional because it represents the introduction of vaginal mesh use for treatment of POP and thus allows for a fairer comparison of the proportion of complications that result from the mesh that was used for SUI vs POP. Qualifying index surgeries included the following procedures during which synthetic mesh was placed (cases of biologic mesh use were not considered): (1) midurethral slings, (2) transvaginal mesh, kit or nonkit (TVM), (3) sacrocolpopexies, and (4) any combinations of 1-3. It was not required for the index surgery to have been performed at the study site. Subjects were included if they came to the study site for evaluation and/or management of a mesh-related complication by December 31, 2012, regardless of the type of treatment (eg, inpatient vs outpatient, conservative vs invasive), if any, that had been received at each respective study site.

For all eligible subjects, the following information was collected: demographics, medical history, information about the index surgery, nature of the synthetic mesh complication, management of the synthetic mesh complication, and classification of the mesh complication. Demographic and medical history data included age, race, parity, height, weight, hormonal status, smoking status, and relevant comorbidities (chronic steroid use, diabetes mellitus, and connective tissue disorders). Index surgery data included the date of the index surgery, location (whether it occurred at the study site), indication (SUI, POP, or both), exact procedure, approach, type/brand of synthetic mesh

that was used, and location of synthetic mesh placement. In the event that a patient had multiple procedures with synthetic mesh during the same surgery or had temporally separated surgeries that involved the placement of synthetic mesh, selection of the designated "index surgery" was left to the discretion of the trained study personnel and his/her professional opinion of which procedure was most likely directly related to the resulting complication. All perioperative complications during the index procedure (including bladder injury, bowel injury, hemorrhage, abscess, or other) and any concomitant procedures were also recorded.

The date of first examination at the study site for evaluation/management of the mesh complication and all symptoms were recorded. All management interventions (including observation only, medications, physical therapy, in-office surgery, and/or operating room surgery that required anesthesia) were recorded in chronologic order. If surgery was required for treatment of the complication, details of that treatment surgery, including operating room time, estimated blood loss, and perioperative or postoperative complications that occurred within 6 weeks after surgery were obtained. Posttreatment pain scores at the first follow-up examination that occurred at least 4 weeks after the most invasive intervention and at the last available follow-up examination were also recorded. Finally, the available data were used to classify each patient according to the expanded Accordion classification of general surgical complications, which is a multilevel categorization system that grades postoperative complications by severity and extent of management that includes criteria such as noninvasive vs invasive procedures, organ system failure, anesthesia, and pharmacologic therapy.[19] It is the most widely used postoperative complication classification system across multiple fields of study and is therefore appropriate for the assessment of mesh-related complications.

Study data were collected centrally and managed with the use of REDCap electronic data capture tools that are hosted by the data-coordinating center, Cleveland Clinic. All data were analyzed with JMP software (version 9; SAS Institute Inc, Cary, NC.) All missing data points were treated as missing and not imputed. Many outcomes are descriptive and, accordingly, only appropriate summary statistics were reported. When data are compared across index surgery group types (eg, sling only, TVM with sling, TVM without sling, and sacrocolpopexy with or without sling) pairwise comparisons that always used "sling only" as the reference group were calculated with the χ^2 test (Fisher exact test, 2-tailed).

TABLE 2
Study subject demographics (n = 347)

Variable	Measure
Age at time of index surgery, y[a]	56.6 ± 12.7
Median (range)	56.4 (24.9–91.8)
Race, n (%)[b]	
Non-Hispanic white	226 (65.3)
African American	11 (3.2)
Hispanic	8 (2.3)
Asian	1 (0.3)
Other	7 (2)
Do not know/not recorded	93 (26.9)
Parity, n[c]	2.6 ± 1.24
Median (range)	2 (0–9)
≥1, %	97.9
Body mass index, kg/m^2[d]	28.4 ± 5.3
Median (range)	27.6 (19.3–43.5)
Hormone status, n (%)[b]	
Premenopausal	73 (21.1)
Postmenopausal, do not know hormone replacement status	96 (27.7)
Postmenopausal, not on hormone replacement	104 (30.1)
Postmenopausal, on hormone replacement	40 (11.6)
Do not know/not reported	33 (9.5)
Smoking status, n (%)[b]	
Never	212 (61.3)
Previous	73 (21.1)
Current	43 (12.4)
Do not know/not reported	18 (5.2)
Comorbidities, n (%)[e]	
Chronic steroid use	7 (2)
Diabetes mellitus	23 (6.6)
Connective tissue disease	0

[a] n = 319; [b] n = 346; [c] n = 331; [d] n = 293; [e] n = 347.

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014.

RESULTS

A total of 693 potential subjects across the 4 tertiary referral centers were

TABLE 3
Complaints at evaluation by index surgery type (n = 347)

Complaint	Total, n (%)	Procedure, n (%)				
		Sling only (n = 173)	Transvaginal mesh with sling (n = 76)	Transvaginal mesh without sling (n = 72)	Transvaginal mesh with or without sling combined (n = 148)	Sacral colpopexy with or without sling (8/25 have sling)
Mesh erosion/ exposure/extrusion	148 (42.7)	52 (30.1)	46 (60.5)[a]	35 (48.6)[a]	81 (54.7)	14 (56)[a]
Pain						
Pelvic pain	120 (34.6)	44 (25.4)	29 (38.2)[a]	38 (52.8)[a]	67 (45.3)	9 (36)
Leg pain	9 (2.6)	2 (1.2)	1 (1.3)	5 (6.9)[a]	6 (4.1)	1 (4)
Back pain	9 (2.6)	2 (1.2)	1 (1.3)	6 (8.3)[a]	7 (4.7)	0
Groin pain	14 (4)	4 (2.3)	4 (5.3)	6 (8.3)	10 (6.8)	0
Any type of pain symptom	125 (36)	46 (26.6)	29 (38.2)	40 (55.6)[a]	69 (46.6)	10 (40)
Vaginal						
Dyspareunia	104 (30)	34 (19.7)	35 (46.1)[a]	31 (43.1)[a]	66 (44.6)[b]	4 (16)
Pain to male partner during vaginal intercourse	37 (10.7)	14 (8.1)[11]	13 (17.1)[11]	7 (9.7)	20 (13.5)	3 (12)
Vaginal constriction	15 (4.3)	1 (0.6)	7 (9.2)[a]	6 (8.3)[a]	13 (8.8)	1 (4)
Vaginal discharge	32 (9.2)	8 (4.6)	7 (9.2)	6 (8.3)	13 (8.8)[b]	10 (40)
Vaginal spotting	39 (11.2)	8 (4.6)	16 (21.1)[a]	11 (15.3)[a]	27 (18.2)	4 (16)[a]
Any type of vaginal symptom	160 (46.1)	47 (27.2)	47 (61.8)[a]	46 (63.9)[a]	93 (62.8)	19 (76)[a]
Recurrent symptoms						
Recurrent or de novo prolapse	49 (14.1)	7 (4)	18 (23.7)[a]	22 (30.6)[a]	40 (27.0)[b]	2 (8)
Recurrent or de novo incontinence	87 (25.1)	51 (29.5)	27 (35.5)	6 (8.3)[a]	33 (22.3)	3 (12)
Infection						
Localized/abscess	37 (10.7)	21 (12.1)	4 (5.3)	9 (12.5)	13 (8.8)	3 (12)
Systemic	0	0	0		0	0
Lower urinary tract						
Fistula	6 (1.7)	1 (0.6)	3 (3.9)	2 (2.8)	5 (3.4)	0
Urinary obstruction	66 (19)	56 (32.4)	7 (9.2)[a]	1 (1.4)[a]	8 (5.4)	2 (8)[a]
Voiding dysfunction	98 (28.2)	60 (34.7)	20 (26.3)	15 (20.8)[a]	35 (23.6)	2 (8)[a]
Painful voiding	20 (5.8)	13 (7.5)	3 (3.9)	3 (4.2)	6 (4.1)	0
New onset incontinence	25 (7.2)	3 (1.7)	1 (1.3)	17 (23.6)[a]	18 (12.2)	4 (16)[a]
Other	26 (7.5)	14 (8.1)	5 (6.6)	6 (8.3)	11 (7.4)	1 (4)
Any lower urinary tract symptom	171 (49.3)	96 (55.5)	33 (43.4)	33 (45.8)	66 (44.6)	8 (32)[a]

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014. *(continued)*

TABLE 3
Complaints at evaluation by index surgery type (n = 347) *(continued)*

Complaint	Total, n (%)	Procedure, n (%)				
		Sling only (n = 173)	Transvaginal mesh with sling (n = 76)	Transvaginal mesh without sling (n = 72)	Transvaginal mesh with or without sling combined (n = 148)	Sacral colpopexy with or without sling (8/25 have sling)
Lower gastrointestinal tract						
Fistula	0	0	0	0	0	0
Fecal incontinence	6 (1.7)	1 (0.6)	0	5 (6.9)[a]	5 (3.4)	0
Obstructive defecation/tenesmus	16 (4.6)	2 (1.2)	5 (6.6)[a]	8 (11.1)[a]	13 (8.8)	1 (4)
Painful defecation/ dyschezia	2 (0.6)	0	1 (1.3)	1 (1.4)	2 (1.4)	0
Other	1 (0.3)	0	1 (1.3)	0	1 (0.7)	0
Any lower gastrointestinal symptom	22 (6.3)	3 (1.7)	7 (9.2)[a]	11 (15.3)[a]	18 (12.2)	1 (4)
Nerve injury	5 (1.4)	1 (0.6)	2 (2.6)	0	2 (1.4)	2 (8)
Obturator	1 (0.3)	0	1 (1.3)	0	1 (0.7)	0
Pudendal	1 (0.3)	1 (0.6)	0	0	0	0
Sciatic	1 (0.3)	0	0	0	0	1 (4)
Do not know/ not reported	2 (0.6)	0	1 (1.3)	0	1 (0.7)	1 (4)
Other	0	0	0	0	0	0

[a] Statistically significant difference at $\alpha = .05$ with the use of the χ^2 test (2 × 2 table, Fisher exact test, 2-tailed) that compared transvaginal mesh with sling, transvaginal mesh without sling, and sacral colpopexy each against sling only; [b] Statistically significant difference at $\alpha = .05$ with the use of the χ^2 test (2 × 2 table, Fisher exact test, 2-tailed) that compared transvaginal mesh with or without sling against sacral colpopexy.

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014.

identified with the Current Procedural Terminology and International Classification of Diseases, 9th Revision, codes listed in Table 1. Ultimately, 347 subjects (50.1%) met the eligibility criteria. Baseline demographics of the study population are provided in Table 2. Most patients were postmenopausal, with a mean age of 56.6 ± 12.7 years at the time of the index surgery. The overwhelming majority of the women (97.9%) were multiparous. Only 12.4% of them were known current smokers at the time of their index surgery; 6.6% of them had diabetes mellitus, and 2% of them used chronic steroids for another medical condition.

During the index surgery, 49.9% of the women underwent a procedure for SUI only (ie, sling); 25.6% of the women underwent a procedure for POP only, and 24.2% of the women underwent a procedure for both SUI and POP. Of those who had a POP procedure that involved synthetic mesh, 85.5% procedures were TVM, and 13.9% procedures were sacrocolpopexies. Just over one-half of the study subjects (50.4%) who received evaluation/management of a complication underwent their index surgery at that same study site.

Median time from index surgery to first examination at a participating tertiary referral study site was 5.8 months (range, 0–65.2 months); 25.7% of the women were seen at another facility before being seen at 1 of these sites. The most common complaints were mesh erosion (42.7%), pelvic pain (34.6%), and dyspareunia (30%), although most women (70.3%) had with >1 distinct symptom or complaint (median, 2; range, 0–8). Patients who were seen after TVM or sacrocolpopexies were significantly more likely to have mesh erosion and vaginal symptoms, compared with those who received a sling only (Table 3). Patients with complications after TVM had a significantly higher occurrence of pelvic pain, dyspareunia, vaginal spotting, vaginal constriction, and obstructed defecation than those after sling alone (Table 3). Compared with TVM, patients with complications after sacrocolpopexies were significantly more likely to complain of vaginal discharge but less likely to complain of dyspareunia or recurrent POP (Table 3). Voiding dysfunction was most common in those women who received a sling only (Table 3).

Symptoms were also grouped by severity with the use of the expanded Accordion classification. Overall, 77% of the women had a grade 3 or 4, which is a "severe" complication, according to the Accordion classification (Table 4). Patients whose index surgery involved TVM were significantly more likely to have a grade 4 complication (return to operating room/general anesthesia) than those who received a sling only (Table 4).

The median number of interventions/ treatments for each woman with a

TABLE 4
Complaint severity at evaluation according to the Accordion Expanded Classification[20] by index surgery type (n = 347)

		Procedure, n (%)			
Grade	Total, n (%)	Sling only (n = 173)	TVM with sling (n = 76)	TVM without sling (n = 72)	Sacral colpopexy with or without sling (8/25 have sling)
1[a]	39 (11.2)	27 (15.6)	4 (5.3)[b]	7 (9.7)	1 (4)
2[c]	25 (7.2)	14 (8.1)	2 (2.6)	6 (8.3)	3 (12)
3[d]	52 (15)	37 (21.4)	8 (10.5)[b]	3 (4.2)[b]	4 (16)
4[e]	215 (62)	88 (50.9)	58 (76.3)[b]	51 (70.8)[b]	17 (68)
5[f]/6[g]	0	0	0	0	0
Cannot be classified	16 (4.6)	7 (4)	4 (5.3)	5 (6.9)	0

[a] Mild complication that requires only minor invasive procedures that can be done at the bedside; [b] Statistically significant difference at $\alpha = .05$ with the use of χ^2 test (2 × 2 table, Fisher exact test, 2-tailed) comparing transvaginal mesh with sling, transvaginal mesh without sling, and sacral colpopexy each against sling only; [c] Moderate complication that requires pharmacologic treatment with drugs other than those allowed for minor complications (antibiotics, blood transfusions, and total parenteral nutrition); [d] Severe complication that requires an endoscopic, interventional procedure or reoperation without general anesthesia; [e] Severe complication that requires management by an operation with general anesthesia; [f] Severe complication: organ system failure; [g] Death.

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014.

complication was 2 (range, 1–9); 60% of the women required ≥2 interventions. The initial treatment intervention was surgical for 49% and nonsurgical for 51%. Of those who initially were treated nonsurgically, 59.3% went on to surgical intervention (3.8% in-office, 90.5% in the operating room, and 5.7% both in-office and operating room). Of the women who initially had an in-office trimming of mesh, 73.3% eventually went to the operating room. The median number of surgeries per patient during the study time period was 1 (range, 0–6); 20.7% of the women required >1 surgery, and 7.8% of the women required >2 surgeries. Compared with sling-only patients, a lower proportion of patients whose index surgery involved TVM with sling underwent medical treatment first. Of the patients who did receive medical treatment, a higher proportion of women with TVM underwent surgery at the study site, compared with sling-only patients (Table 5). For those patients who did undergo surgical intervention in the operating room for treatment of their complication, trimming of mesh/partial mesh excision (area of eroded mesh excised only) was the most common first surgical procedure that was performed (50.9%), whereas complete mesh excision (removal of the entire intravaginal portion of mesh to the lateral arms where they leave the pelvis) was the next most common first procedure (26.9%; Table 6). Complete mesh excision as the first operating room intervention was more common in those who had TVM alone, compared with those that had sling alone (Table 6).

Comment

The purpose of this study was to describe the evaluation and management of complications from synthetic mesh after surgery for SUI and POP at 4 US tertiary referral centers. Several significant trends were noted. First, approximately one-half of the women (49.3%) who sought treatment of a mesh-related complication at a tertiary referral center actually underwent their index procedure at a facility other than that tertiary referral center. This trend has been reported in other studies as well.[12] This raises the potential concern that physicians who perform these mesh procedures may not be aware of the complications their patients experience and that these providers may be responsible for future mesh-related complications with no awareness of the existing magnitude of the issue.

Second, several trends were identified that suggested that the synthetic mesh that is used in the application of slings for the treatment of SUI has a more predictable and less severe course of complications compared with the synthetic mesh that is used for the management of POP. For instance, those patients whose index surgery involved a sling only were significantly less likely to experience an Accordion classification severity grade 4, which is a complication that requires a return to the operating room with general anesthesia, than were those women whose index surgery involved the use of TVM. Furthermore, complications after TVM tend to be more severe, are more chronic in nature, and can be more difficult to treat. For instance, mesh erosion, pelvic pain, dyspareunia, vaginal constriction, vaginal spotting, and obstructive defecation were all significantly more common after an index surgery with TVM than 1 with sling only. Contrarily, urinary obstruction and voiding dysfunction were the only complications that were observed significantly more frequently in those women whose index surgery involved sling only, which suggests that these symptoms may be more related to the actual incontinence procedure rather than the use of mesh for treatment. Additionally, those women with complications after a sling-only procedure were treated more often with medical treatment first and rarely required surgical reintervention. Such findings are important because increased interest in this issue from the Food and Drug Administration potentially threatens the continued use of synthetic mesh in pelvic floor surgery.

Despite the distinction in complication severity between TVM and sling-only procedures, complications that are associated with mesh in general are very concerning. Most patients (60%) received 2 or more unique interventions; even then, there was no guarantee of symptom resolution. Perhaps more surprisingly, 79.3% of all subjects underwent at least 1 surgical intervention, whether in-office or in the operating room. Of those who required any

TABLE 5
Management by index surgery type (n = 347)

Variable	Total, n (%)	Procedure, n (%)			
		Sling only (n = 146)	Transvaginal mesh with sling (n = 76)	Transvaginal mesh without sling (n = 72)	Sacral colpopexy with or without sling (8/25 have sling)
Proportion of women who underwent ≥2 reintervention surgeries	72 (20.1)	34 (23.3)	23 (30.3)	13 (18.1)	2 (8)
Proportion of women who underwent medical treatment first	177 (51)	96 (55.5)	26 (34.2)[a]	36 (50)	18 (72)
Proportion of women who did not undergo any reintervention surgery at study site	72 (20.1)	42 (24.3)	8 (10.5)[a]	17 (23.6)	5 (20)

[a] Statistically significant difference at $\alpha = .05$ with the use of χ^2 test (2 × 2 table, Fisher exact test, 2-tailed) that compared transvaginal mesh with sling, transvaginal mesh without sling, and sacral colpopexy each against sling only.

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014.

surgery, nearly one-quarter of the women (26.2%) required >1 surgery. These results suggest that mesh-related complications that are observed at tertiary referral centers are regularly severe enough to require surgical reintervention. Prospective studies that observe patients from the time of evaluation with complication through their various treatment episodes with measurable outcomes of symptom resolution will be necessary to answer the question of how to best manage various synthetic mesh complications and validate whether the high surgical reintervention rate in this study was justified.

Limitations of this study include its retrospective nature and the biases that are inherent in such an approach. Additionally, the use of coding queries to identify study subjects poses a challenge because not all data are always captured when they should be. Perhaps most importantly, there is no denominator for the total number of patients who underwent an SUI or POP procedure with synthetic mesh. Thus, we can make no comments about the rate at which such complications occur. We can only observe that when they do occur, the nature of the complication is usually severe and often requires surgical intervention. Nonetheless, this information

TABLE 6
Details of first surgical procedure to manage mesh complications

Variable	Total, n (%)[a]	Procedure, n (%)			
		Sling only (n = 128)	Transvaginal mesh with sling (n = 67)	Transvaginal mesh without sling (n = 55)	Sacral colpopexy with or without sling (n = 20)
Trimming of mesh/ partial excision[b]	138 (50.9)	59 (46.1)	37 (55.2)	27 (49.1)	15 (75)[c]
Release of mesh arms[d]	49 (18.1)	19 (14.8)	16 (23.9)	13 (23.7)	1 (5)
Complete mesh excision[e]	73 (26.9)	27 (21.1)	19 (28.4)	24 (43.6)[c]	2 (10)
Recurrent prolapse treatment	63 (23.2)	9 (7)	24 (35.8)	26 (47.3)	4 (20)
Recurrent incontinence treatment	40 (14.8)	14 (10.9)	9 (13.4)	14 (25.5)[c]	3 (15)
Other surgery	56 (20.1)	28 (21.9)	12 (17.9)	12 (21.8)	4 (20)

[a] n = 271; 275 women had surgery, 4 of which were in-office only); [b] Area of eroded mesh only excised[19]; [c] Statistically significant difference at $\alpha = .05$ with the use of χ^2 test (2 × 2 table, Fisher exact test, 2-tailed) that compared transvaginal mesh with sling, transvaginal mesh without sling, and sacral colpopexy each against sling only; [d] Incision made in ≥1 of the lateral mesh arms to release tension; [e] Removal of the entire intravaginal portion of the mesh to the lateral arms where they leave the pelvis.

Abbott. Evaluation and management of complications from synthetic mesh. Am J Obstet Gynecol 2014.

is helpful in depicting worst-case scenario outcomes, which can be central to informed consent discussions and decision-making. ■

REFERENCES

1. Olsen A, Smith V, Bergstrom J, et al. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol 1997;89:501-6.
2. Hendris SL, Clark A, Nygaard I, et al. Pelvic organ prolapse in the Women's Health Initiative: gravity and gravidity. Am J Obstet Gynecol 2002;186:1160-6.
3. Mistrangelo E, Mancuso S, Nadalini C, et al. Rising use of synthetic mesh in transvaginal pelvic reconstructive surgery: a review of the risk of vaginal erosion. J Minim Invasive Gynecol 2007;14:564-9.
4. Hiltunen R, Nieminen K, Takala T, et al. Low-weight polypropylene mesh for anterior vaginal wall prolapse: a randomized controlled trial. Obstet Gynecol 2007;110(suppl):455-62.
5. Nguyen JN, Burchette RJ. Outcome after anterior vaginal prolapse repair: a randomized controlled trial. Obstet Gynecol 2008;111:891-8.
6. Diwadkar GB, Barber MD, Feiner B, et al. Complication and reoperation rates after apical vaginal prolapse surgical repair. Obstet Gynecol 2009;113:367-73.
7. Firoozi F, Ingber MS, Moore CK, et al. Purely transvaginal /perineal management of complications from commercial prolapse kits using a new prostheses/grafts complication classification system. J Urology 2012;187:1674-9.
8. Tijdnik MM, Vierhout ME, Heesakkers JP, et al. Surgical management of mesh-related complications after prior pelvic floor reconstructive surgery with mesh. Int Urogynecol J 2011;22:1395-404.
9. Nguyen JN, Jakus-Waldman SM, Walter AJ, et al. Perioperative complications and reoperations after incontinence and prolapse surgeries using prosthetic implants. Obstet Gynecol 2012;119:539-46.
10. Jia X, Glazener C, Mowatt G, et al. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systemic review and meta-analysis. BJOG 2008;115:1350-61.
11. Marqulies RU, Lewicky-Gaupp C, Fenner DE, et al. Complications requiring reoperations following vaginal mesh kit procedures for prolapse. Am J Obstet Gynecol 2008;199:678.e1-4.
12. Ridgeway B, Walters MD, Paraiso M, et al. Early experience with mesh excision for adverse outcomes after transvaginal mesh placement using prolapse kits. Am J Obstet Gynecol 2008;199:703.e1-7.
13. Sung VW, Rogers RG, Schaffer JI, et al. Graft use in transvaginal pelvic organ prolapse repair: a systematic review. Obstet Gynecol 2008;112:1131-42.
14. Chen CC, Ridgeway B, Paraiso MF. Biologic grafts and synthetic meshes in pelvic reconstructive surgery. Clin Obstet Gynecol 2007;50:383-411.
15. Deffieux X, de Tayra R, Huel C, et al. Vaginal mesh erosion after transvaginal cystocele repair using Gynemesh or Gynemesh-Soft in 138 women: a comparative study. Int Urogynecol J Pelvic Floor Dysfunct 2007;18:73-9.
16. Baessler K, Hewson AD, Tunn R, et al. Severe mesh complications following intravaginal slingplasty. Obstet Gynecol 2005;106:713-6.
17. US Food and Drug Administration. FDA public health notification: serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence. October 20, 2008. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/UCM061976. Accessed July 31, 2012.
18. US Food and Drug Administration. FDA safety communication: update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. July 13, 2011. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm. Accessed July 31, 2012.
19. Barber MD. Surgical techniques for removing problematic mesh. Clin Obstet Gynecol 2013;56:289-302.
20. Strasberg SM, Linehan DC, Hawkins WG. The accordion severity grading system of surgical complications. Ann Surg 2009;250:177-86.